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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,263	02/19/2004	Yoshiyuki Inada	087147-0450	3131

22428 7590 11/30/2004

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EXAMINER	
LAMBKIN, DEBORAH C	

ART UNIT	PAPER NUMBER
1626	

DATE MAILED: 11/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/781,263	INADA ET AL.	
	Examiner	Art Unit	
	Deborah C Lambkin	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

DEBORAH C. LAMBKIN
PRIMARY EXAMINER

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 1-10

are pending in the reissue application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treament of some diseases, does not reasonably provide enablement for " prophylaxis" of any of the diseases listed far more any angiotensin II-mediated diseases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The data in the instant specification show only a change in hypertension when the combination of the two drugs are co-administered. It is not seen how this case of treatment can be extrapolated to the "prophylaxis" of all or any angiotensin II-mediated disease, especially Alzheimer's. Applicant has failed to show either by data in the instant specification or documentary evidence in the art that the mere showing of the treatment of hypertension can enable the prevention of all or any other angiotensin II-mediated disease. As a result, it would require undue experimentation for one of ordinary skill in the art to determine which diseases are preventable by the instant drug

combination, hence the instant specification is not commensurate in scope to the invention as claimed.

This rejection can be overcomed is by deleting "prophylaxis" from the claims.

Claims 4 and 7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for one diuretic, HCT, and one calcium channel antagonist, MDP, does not reasonably provide enablement for all and any compound having diuretic or calcium channel antagonistic activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The mere showing of one example of each class of drugs cannot be reasonably extrapolated to include all and any drug in said class; this is essentially reaching through into the future to include compounds yet to be discovered. Furthermore, applicant is claiming synergism (unexpected results) of two known drugs for the same use which ordinarily is known to give an additive effect (expected results), hence one cannot extrapolate what is expected to be unexpected in the absence of actual data.

As a result, these terms "any compound having diuretic or calcium channel antagonistic activity" is not sufficiently enabled by the instant specification and therefore would require undue experimentation for one of ordinaty skill in the art to determine which combinations of the instant compound and a particular diuretic or calcium channel antagonist would work as claimed.

This rejection may be overcomed by limiting these terms to the actual compounds, that is the diuretic or calcium channel blocker found in claims 5 and 6.

Claim 1 and 4-7 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of hypertension and maybe a few other similar disorders, does not reasonably provide enablement for all and any "angiotensin II-mediated diseases" such as those listed by applicant, see Alzheimer's disease, for example. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicant has not provided sufficient evidence either by showing more data or by way of reference to the state of the art to support that treating hypertension could be extrapolated to treating all or any angiotensin II-mediated disease. It is not known in the art that one drug can treat both hypertension and Alzheimers at the same time, let alone any angiotensin II-mediated disease. Furthermore, applicant's extrapolation from hypertension to any angiotensin II-mediated disease is simply a case of reaching through which is an impermissible standard.

As a result, one of ordinary skill in the art would have to experiment unduly to determine which diseases outside the ones actually enabled would be treatable as claimed.

This rejection could be overcomed by limiting the claims to Markush language in which the diseases listed are similar to hypertension, maybe circulatory diseases for example.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims contain disorders such as "indisposition" which is not clear as to what it means. Also, sensory disturbances "including" Alzheimer's is indefinite since it is not clear what is excluded.

This rejection can be overcomed by deleting these terms from the claims.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims contain the word "mediated" which is considered vague and indefinite because it is not clear if it is a direct correlation or part of a cascade situation where there is no direct involvement. As a result, the metes and bounds of the term mediated cannot be fully ascertained.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted

by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8, 1-15 and 1-3 of U.S. Patent Nos. 5,721,263; 5,958,961; and 6,228,874, respectively. Although the conflicting claims are not identical, they are not patentably distinct from each other because they cross embrace some of the same subject matter.

Patent 5,721,263 covers the same three benzimidazole compounds with manidipine hydrochloride for treating hypertension which reads on the instant broad terms " calcium channel blocker " and " angiotensin II-mediated diseases". Likewise, Patent 5,958,961 covers the generic benzimidazole compounds and the specific diuretic, HCT, or the specific calcium channel blocker, manidipine, for treating hypertension which embraces the instant benzimidazole compounds and reads on the broad terms, calcium channel blocker and angiotensin II-mediated diseases. Likewise, Patent 6,228,874 covers the same three benzimidazole compounds with the diuretic, furosemide, which reads in the instant generic term, diuretic.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Naka et al (EP 0459136 A1) in view of Chakravarty et al (EP 0400835 A1).

Naka et al teach the instant benzimidazole compounds for treating angiotensin II-mediated diseases such as hypertension (see pages 2-3).

Naka et al do not teach that these benzimidazole compounds can be combined with a diuretic or calcium channel blocker for treating the same angiotensin II-mediated diseases.

Chakravarty et al teach essentially the same benzimidazole compounds (see Formula I) of Naka et al for the same use wherein they can further be combined with other anti-hypertensives such as diuretics, for example hydrochlorothiazide (pg.26, line 26), or calcium channel blockers, for example furosemide (pg.26, line 30).

Consequently, it would have been prima facie obvious to one having ordinary skill in the art at the time the application was filed to combine two known anti-hypertensives for treating hypertension, or specifically in this case, a benzimidazole having angiotensin II activity with a diuretic or calcium channel blocker, and expect the resultant combination to have an additive effect at a lower dosage because this

expedient or combining is routine and have already been done in the art showing the same expected additive effect, all in the absence of some unobvious or unexpected results.

No unobvious or unexpected results are seen.

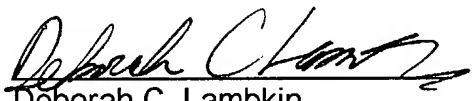
Claims 4-10 are rejected under 35 U.S.C. 251 as being an improper recapture of broadened claimed subject matter surrendered in the application for the patent upon which the present reissue is based. See *Pannu v. Storz Instruments Inc.*, 258 F.3d 1366, 59 USPQ2d 1597 (Fed. Cir. 2001); *Hester Industries, Inc.* v. *Stein, Inc.*, 142 F.3d 1472, 46 USPQ2d 1641 (Fed. Cir. 1998); *In re Clement,* 131 F.3d 1464, 45 USPQ2d 1161 (Fed. Cir. 1997); *Ball Corp.* v. *United States*, 729 F.2d 1429, 1436, 221 USPQ 289, 295 (Fed. Cir. 1984). A broadening aspect is present in the reissue which was not present in the application for patent. The record of the application for the patent shows that the broadening aspect (in the reissue) relates to subject matter that applicant previously surrendered during the prosecution of the application. Accordingly, the narrow scope of the claims in the patent was not an error within the meaning of 35 U.S.C. 251, and the broader scope surrendered in the application for the patent cannot be recaptured by the filing of the present reissue application.

Applicant is attempting to recapture the broad terms in the instant application which were present and subsequently cancelled in the parent (see 08/254,541; 8/351,011) to overcome a 112/1 rejection. Specifically, the terms "diuretic", "calcium

channel antagonists or blocker" and " angiotensin II- mediated diseases" were previously presented, examined, rejected and cancelled.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah C. Lambkin whose telephone number is 571-272-0698.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane, can be reached on 571-272-0699.



Deborah C. Lambkin
Primary Patent Examiner
Art Unit 1626

DEBORAH C. LAMBKIN
PRIMARY EXAMINER